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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,175	09/04/2001	Nobuhiko Ogura	Q65952	9850

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,175

Applicant(s)

OGURA, NOBUHIKO

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 04 December 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.



DETAILED ACTION

1. Applicant's amendment filed 12/4/02 in Paper No. 6 is acknowledged and entered.
Claims 23-41 are canceled. Claims 2-22 are amended. Claims 1-22 are pending.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 12/04/02 has been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.
3. The Patent and Trademark Office no longer makes drawing changes. See 1017 O.G. 4.
It is applicant's responsibility to ensure that the drawings are corrected. Corrections must be made in accordance with the instructions below.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. **Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red

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ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Withdrawn Rejections

4. The previous rejections 35 USC 112, second paragraph, for claims 2-22 have been withdrawn in view of applicant's amendments of claims 2-22.
5. The previous rejections under 35 USC 102(b) as being anticipated by Ullman et al. (US Patent 6,103,537) for claims 1-18 and 22 have been withdrawn in view of applicant's amendments of argument that Ullman et al. does not disclose probes spotted on a substrate.
6. The previous rejections under 35 USC 103(a) as being obvious over Ullman et al. (US Patent 6,103,537) in view of Hassard et al. (US Patent 6,103,533) for claims 19-21 have been withdrawn in view of applicant's argument that Ullman et al. does not disclose probes spotted on a substrate.
7. Upon further consideration, the following new grounds of rejection are made as follows. Therefore, this Office action is a non-final rejection.

New Rejections

8. Claims 1-22 are treated on the merit in this Office Action.

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claim recites a biochemical analyzing method. The method steps comprise of fixing the probes on a substrate, binding a target with the probes to capture the target, fractionating the captured target, detecting the fractionated target, and quantitatively analyzing the detected target. The probes of method step of fixing the probes on a substrate are one-dimensionally spotted on the substrate to form a plurality of spots.

The specification disclosure does not sufficiently teach that the probes are one-dimensionally spotted on the substrate to form a plurality of spots.

The specification description is directed to a biochemical analysis unit that is three-dimensionally scanned with the laser beam emitted from the laser stimulating ray source and light released from the biochemical analysis unit is led to the light detector using the confocal optical system. It is possible to lead only light released from two-dimensionally distributed

targets by being captured by one-dimensionally spotted probes and electrophoresed in the electrophoresis section to the light detector (pg. 15, lines 3-11). Therefore, the specification does not teach spotting the probes one-dimensionally on the substrate to form a plurality of spots.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

In this present instance, the specification disclosure clearly does not teach the scope of one-dimensional spotting of the probes on the substrate to form a plurality of spots. Further, the specification does not define the method of "one-dimensional spotting".

12. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The instant claims recite a biochemical analyzing method. The method steps comprise of fixing the probes on a substrate, binding a target with the probes to capture the target, fractionating the captured target, detecting the fractionated target, and quantitatively analyzing

the detected target. The probes of method step of fixing the probes on a substrate are one-dimensionally spotted on the substrate to form a plurality of spots. The detection of the fractionated target uses an area sensor.

The recitation of 'an area sensor' claimed in claim 20, have no clear support in the specification and the claims as originally filed. The specification in page 14 and 15 disclosed 'the light detector using the confocal optical system' (pg. 14, lines 16-17; pg. 15, lines 6-7) is not support for 'an area sensor'. Because the narrow limitation of the specification recites a confocal optical system, does not support the broad limitation of the claim, which recites an area sensor. Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation an area sensor.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

13. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 10 recites the probes are one-dimensionally spotted on the substrate.

Clarification is requested because it is unclear what is a one-dimensional spotting.

b) Claim 19 recites the limitation "the fractionated target" in line 2. There is insufficient antecedent basis for this limitation in claim 10.

c) Claim 20 recites the limitation "the fractionated target" in line 2. There is insufficient antecedent basis for this limitation in claim 10.

d) Claim 21 recites the limitation "the fractionated target" in line 2. There is insufficient antecedent basis for this limitation in claim 11.

Claim Rejections - 35 USC § 102

14. Claims 1-8, 12-18, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman et al. (US Patent 6,103,537).

"The present claim recites a biochemical analyzing method. The method steps comprise of fixing the probes on a substrate, binding a target with the probes to capture the target, fractionating the captured target, detecting the fractionated target, and quantitatively analyzing the detected target."

Ullman teaches a method of capillary electroseparation specific binding assay (col. 4, lines 33-51). This method includes applying an electric potential to achieve electroseparation of the free and bound labeled species (col. 23, lines 17-38). In Ullman, the angle is 0° and the direction of migration is affected by the direction or orientation of the channel formed on a surface (col. 4, lines 47-50). A member of the specific binding pair (probe) is bound to synthetic particles (substrate) (col. 5, lines 8-16) (fixing the probe on a substrate). The particles are latex, organic, inorganic polymers, or lipid bilayers (col. 13, lines 29-53). The analyte (target) is antigens, antibodies, ligands, or DNA (col. 6, lines 2-15). A label can be bound or unbound to a specific binding pair (col. 11, lines 12-30; col. 9 lines 25-46). The label can be a dye, enzyme, fluorescent molecule or chemiluminescent molecule. The binding determination can be performed qualitatively or quantitatively (col. 20, lines 7-21). The method further discloses employing sieving gel in the electroseparation medium to assist in providing localization of the

bound complex and achieves appropriate separation of free and bound species (col. 24, lines 31-40).

Claim Rejections - 35 USC § 103

15. Claims 1-2 and 9-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfenito (US Patent 6,355,419 B1) in view of Ichie (US Patent 5,796,112).

"The present claim recites a biochemical analyzing method. The method steps comprise of fixing the probes on a substrate, binding a target with the probes to capture the target, fractionating the captured target, detecting the fractionated target, and quantitatively analyzing the detected target. The probes are fixed on the substrate by spotting to form plurality of spots."

Alfenito disclose several different methods of detecting a target nucleic acid species including steps of providing an array of probes affixed to a substrate (col. 2, lines 17-19). The array is prepared by spotting the oligonucleotide probes onto a support (col. 24, lines 46-67; col. 28, lines 2-33). The target nucleic acid is hybridized (binding) to the probe (col. 2, lines 29-31). In one method the target are sorted (fractionated) by an electric field (col. 36, lines 19-33). The probes may be labeled with fluorescent dyes or chemiluminescent systems (col. 14, lines 54-57). Charged-coupled device (CCD) detectors serve as active solid supports that quantitatively detect and image, which is a two-dimensional pattern, the distribution labeled target molecules in probe-based assays (col. 41, lines 20-51).

The method of Alfenito does not expressly disclose that the target is detected by three-dimensional scanning.

Ichie disclose a method of detecting an optical spot of a sample that is labeled with a fluorescent dye (col. 1, lines 38-54). The sample is scanned three-dimensionally or two-dimensionally.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the detection of a target by three-dimensional scanning as taught by Ichie in the method of Alfenito. One of ordinary skill in the art would have been motivated to include the detection of a target by three-dimensional scanning in the method of Alfenito for the advantage of providing an image with more depth. Since both Alfenito and Ichie disclose the method of detecting fluorescent samples (Alfenito: col. 41, lines 20-31; Ichie: col. 1, lines 38-54).

Response to Arguments

16. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct

March 20, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER